Advancing Transfusion and
Cellular Therapies Worldwide

June 23, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852-1448

Docket No. 2004N-0539 "Establishing a Docket for the Development of Plasma Standards Public Workshop"

Dear Docket Manager:

The AABB Task Force on Recovered Plasma (the task force), representing AABB, America's Blood Centers (ABC), American Red Cross (ARC), Blood Centers of America/hemerica (BCA), and the Armed Services Blood Program Office (ASBPO), wishes to comment on the public workshop titled Development of Plasma Standards. The comments address the views of the task force regarding subjects addressed during the workshop.

Background:

The task force's first concern is regarding standards for the licensing for recovered plasma. The task force believes that the Food and Drug Administration (FDA) should set standards for licensing recovered plasma. De facto regulation, through the requirement for a short supply agreement, that currently sets the requirements for this product, is not an appropriate method of control.

The task force's second concern is the definition of recovered plasma. Currently, this term is applied to plasma that is removed from whole blood and intended for further manufacturing. Source plasma is defined as plasma collected by plasmapheresis and intended for further manufacturing. The primary distinction in definition appears to be the intent of the collection and the method of collection. Use of intent as a criterion severely limits the flexibility needed to maximize the utilization of collected blood.

As technology has changed, concurrent plasma is collected with other blood components intended for transfusion (plateletpheresis and red cells by pheresis). This plasma is suitable for

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

use in further manufacturing, but regulations preclude such use because it was not produced from whole blood, nor was it specifically intended for further manufacturing. The task force strongly believes that the FDA should permit the use of concurrent plasma for further manufacturing when the concurrent plasma is collected using an infrequent donation protocol. Further, such plasma should be acceptable even if it was originally labeled as fresh frozen plasma (FFP) and intended for use in transfusion therapy.

A third concern relates to confusion about record retention requirements. Because recovered plasma is not a licensed product, it does not have an established expiration date. Blood banks are now required to keep records indefinitely for any product without an expiration date. All licensed blood components have defined expiration dates and these dates determine the record retention requirements. Recovered plasma should be assigned an expiration date.

The task force formally recommends the following proposed requirements. These are the same requirements that were presented to the Blood Products Advisory Committee (BPAC) on September 1, 200, and were again presented during the public workshop on Development of Plasma Standards.

1) Product Name: The task force recommends that the recovered plasma should be re-named as plasma for manufacture.

2) Donor Qualification: Donors must meet the same criteria as allogeneic whole blood donors. Plasma collected concurrently with automated collection of cellular products for transfusion by apheresis is collected according to an FDA memorandum on 3/10/95, "Revision of FDA Memorandum of August 24, 1982: Requirements of Infrequent Plasmapheresis Donors."

3) Methods of Preparation: Multiple methods of preparation are acceptable. Plasma for manufacture may be separated from whole blood, or prepared from infrequent plasmapheresis concurrent with automated collection of cellular products for transfusion, or from infrequent plasmapheresis. It is also acceptable to convert plasma for transfusion (FFP) to plasma for manufacture.

   Plasma for manufacture prepared by separation from whole blood can be made anytime during the dating period of whole blood and labeled at the time of preparation. Similarly, plasma for transfusion may be converted to plasma for manufacture anytime during its dating period, or up to one year after outdate as a transfusible component.

4) Expiration Date: The date of expiration of plasma for manufacture is two years from the date of the actual collection.

5) Testing for Infectious Disease: Plasma for manufacture has the same infectious disease testing requirements as whole blood except a negative result for anti-HBc and/or a negative result for anti-HTLV I/II are not required.

6) Labeling: The label should on the product should include –

   - Product Name: *Plasma for Manufacture*
   - Statement of Freezing Time: *Frozen Within __ Hours After Phlebotomy*
   - Caution Statement: Caution: *For Manufacturing Use Only Into Injectable Products*
   - Product Code: *From Uniform Labeling Guidelines or ISBT 128*
   - Amount: *Total volume or weight of plasma*
   - For whole blood derived plasma for manufacture: *The name and volume of source material, e.g. "From 500 mL CPD Whole Blood."*
   - For plasma for manufacture collected by infrequent plasmapheresis (concurrent cellular or plasmapheresis): *The total type and volume of anticoagulant used.*
   - Storage temperature: *Store at -18°C or colder*
   - Facility Identification: *Name, address and license number of collection facility and name, address and license number of institution where separated (if different than collection facility).*
   - Testing Statement: *The statement "Negative by FDA required tests."*
   - Collection Date: *Month, date and year. (Note: While the collection date on the label is currently proposed, the task force would ultimately request only an expiration date on the product, once that expiration date is established for plasma for manufacture.)*

7) Component Retrieval: Component retrieval (based on subsequent test results or other donor information) shall be the same as those currently required by FDA for source plasma or recovered plasma.

8) Records: Records shall be retained for 10 years.

Please note, this proposal does not specify freezing within a specific time frame, as there are multiple types of products that can become plasma for manufacture. Also, by specifying the time on the label, the fractionator can determine suitability for intended use.

The task force also notes that AABB has been setting voluntary standards for blood banks and transfusion services for more than 50 years. The *BBTS Standards* include quality management concepts with the quality management system providing the framework for organization of the *BBTS Standards*. The *BBTS Standards* are updated on a regular basis based on input from AABB members, the public, and recognized experts in blood banking and transfusion medicine. Therefore, recovered plasma is subject to the same voluntary standards as whole blood.

The AABB Task Force on Recovered Plasma began in 2002 in an effort to work toward the creation of appropriate regulations for recovered plasma and act as active participants in FDA workshops and other discussions related to the issue of recovered plasma. The task force appreciates the opportunity to comment and present our thoughts on standards for recovered plasma. We are prepared to cooperate with the FDA and others in developing comprehensive up-to-date standards for this valuable resource.

If you have any questions, please contact Kay Gregory, MT (ASCP) SBB, at kayg@aabb.org or 910-842-2790.

Sincerely,

Kay Gregory, MT (ASCP) SBB
Director, Regulatory Affairs